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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,205	05/02/2002	Richard A Gambale	B 0410/7284	4832

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EXAMINER

GHERBI, SUZETTE JAIME J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,205

Applicant(s)

GAMBALE, RICHARD A

Examiner

Suzette J. Gherbi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-12, 14 and 16-25 is/are pending in the application.
- 4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12, 14 and 16-18, 22-24 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's RCE dated June 20, 2005 has been received in application serial number 10/048,205. Claims 6, 13, 15, 17 have been canceled. Claims 19-21 have been withdrawn. Claim 25 is new.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 7, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. 5,824,053. Khosravi et al. discloses the invention as currently claimed comprising: A tissue device configured to resist migration with a helically formed coil (see col. 5, line 24) having a rectangular cross-sectional profile (col. 9, line 37) the coil having a plurality of turns and an edge; wherein the barbs are proximally facing; wherein the barbs (44) face radially outward from the coil; stents manufactured from flat sheets of nitinol by chemical etching and then rolling them to form a coil member (col. 6, lines 17-46). However Khosravi et al. does not specify (A) the phrase "formed from a filament" is being treated as product by process as set forth in MPEP

2113 therefore the claim is not limited to the manipulation (formed) only to the structure implied. The burden is shifted to applicant to show an unobvious difference and a statement or argument by the attorney is not factual evidence. See MPEP 716.01 or (B) rounded barbs with a contoured edge. However Khosravi et al. does teach that parts of the edge of the band can be rounded. It would have been obvious to one having ordinary skill in the art at the time the invention was made to also modify the shape of the barbs (44) to be rounded because as disclosed by Khosravi et al. rounded edges are known and are beneficial for example to reduce the risk of injuring tissue and is deemed a design modification.

5. Claims 14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi in view of Summers 5,607,445. Khosravi et al. has been disclosed above noting figure 5a and barb/projection edge, however Ahern does not specify *photochemical etching* process. Summers teach manufacturing a coil device by photo-etching process (col. 9, lines 31-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made because chemical/photo etching are well known methods for forming loops and coils from a blanks to make tubular prosthesis.

6. Claims 8-11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahern in view of Lashinski et al. 5,868,780. Ahern discloses the invention as

claimed noting figure 7 comprising: A tissue implant made of a flexible helical coil having a plurality of *barbs projecting* from the edge. However Ahern does not specify that the spring device be formed from a plurality of materials each having different moduli of elasticity; varying along the springs length. Lashinski et al. teaches that stents can be formed with different materials, varied along the length of the device, which have different yield strengths and having different moduli of elasticity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the device of Ahern and manufacture it with different materials having various moduli of elasticity because it would allow the device to plastically conform to the anatomy of the passageway in which it is to placed.

Allowable Subject Matter

7. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 6/20/05 have been fully considered but they are not persuasive. Applicant has amended the claims and recaps the current invention. Applicant then gives a brief interpretation of each reference cited in the prior office

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action. Applicant contends that Ahern's disclosure is not prior art because applicant published PCT application WO 98/49964 published 11/12/98 and filed 5/4/98 claims priority of earlier filed applications. It is the examiners opinion that the WO 98/49964 does not provide support in the disclosure for the subject matter as claimed (i.e. round barbs or a plurality of barbs projecting from the edge); never the less if applicant wants to rely upon this reference they should see MPEP 715:

715 [R-2] Swearing Back of Reference — Affidavitor Declaration Under 37 CFR 1.131
37 CFR 1.131. Affidavit or declaration of prior invention. (a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. The effective date of a U.S. patent, U.S. patent application publication, or international application publication under PCT Article 21(2) is the earlier of its publication date or date that it is effective as a reference under 35 U.S.C. 102(e). Prior invention may not be established under this section in any country other than the United States, a NAFTA country, or a WTO member country. Prior invention may not be established under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country. Prior invention may not be established under this section if either:

(1) The rejection is based upon a U.S. patent or U.S. patent application publication of a

pending or patented application to another or others which claims the same patentable invention as

defined in § 1.601(n); or

(2) The rejection is based upon a statutory bar.

(b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained.

9. As amended the examiner agrees that there are not barbs projected from the edge of Ahern however independent claim 8 does not recite this limitation.

10. The combination of Ahern and Lashinski et al. does meet the limitation of claims 8-11 and Lashinski et al is utilized to teach the varying moduli of elasticity by utilizing varying material with different yield strengths.

11. Applicant has further amended the claims to recite that the barbs project from the edges. The new rejections above address the amended claims. Applicant argues that Ahern had no motivation to provide rounded barbs. Khosravi et al. teaches that section of the stent can be rounded so as not to injure tissue and it is obvious to one having skill in the art that this rounding can apply to the barbs for the same purpose.

12. Applicant goes on to contend the Khosravi discloses a band and that the barbs are located entirely within the interior opening and do not project from an edge as claimed. It is the examiner's opinion that applicant has only taken one embodiment into consideration. Applicant should view col. 8, lines 60-67 which states "the stent comprises a helical mesh coil ... and a plurality of turns. Stent 40 further comprises a multiplicity of barbs 44 integrally formed with the rectangular lattice so that the barbs project outwardly from the stent". By viewing figure 5A one can see that these barbs in this embodiment are aligned along the edge. Nowhere does the patent state "...are located entirely within the interior opening and do not project from an edge" as applicant argues, therefore the 103 rejection is deemed proper.

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Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

14. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J-J Gherbi
30 June 2005